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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference PCT MS0012Y	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/21493	International filing date (day/month/year) 08 July 2003 (08.07.2003)	Priority date (day/month/year) 11 July 2002 (11.07.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 31/50, 31/495, 31/435, 31/045, 31/05 and US Cl.: 514/252.06, 252.05, 252.01, 248, 247, 277, 730, 731		
Applicant MERCK & CO., INC		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

EPO - DG 1

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

15. 10. 2004

(37)

Date of submission of the demand 09 February 2004 (09.02.2004)	Date of completion of this report 10 August 2004 (10.08.2004)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer <i>Spencer Pradhanabhan</i> Telephone No. 703.308.0198

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/21493

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-150 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____
- ☒ the claims:
pages 151-202 as originally filed
pages NONE as amended (together with any statement) under Article 19
pages NONE filed with the demand
pages NONE filed with the letter of _____
- ☒ the drawings:
pages NONE as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____
- ☐ the sequence listing part of the description:
pages NONE as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 25.1(b)).
- ☐ the language of publication of the international application (under Rule 43.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/21493

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>1-25</u>	YES
	Claims <u>26</u>	NO
Inventive Step (IS)	Claims <u>1-25</u>	YES
	Claims <u>26</u>	NO
Industrial Applicability (IA)	Claims <u>1-26</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claim 26 does not meet the criteria of PCT Article 33(2) because the prior art cited RIPS et al. (Journal of Organic Chemistry (1959), 24, 551-4) in the International Search Report discloses the instant compounds.

Claim 26 does not meet the criteria of PCT Article 33(3) because the prior art cited RIPS et al. (Journal of Organic Chemistry (1959), 24, 551-4) in the International Search Report discloses the instant compounds.

Claims 1-25 meet the criteria of PCT Article 33(2) (novelty) because the cited references, are "A" references that do not disclose and teach the instant invention in claims 1-25.

Claims 1-25 meet the criteria of PCT Article 33(3) (inventive step) because the cited references, are "A" references that do not disclose and teach the instant invention in claims 1-25.

Claims 1-26 meet the criteria of PCT Article 33(4) because the claimed method of binding the $\alpha 2\delta$ subunit of voltage gated calcium channels by administering the instant compound has industrial applicability in the pharmaceutical art.

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NOTE OF INFORMAL COMMUNICATION WITH THE APPLICANT

(PCT Rule 66.6)

International application No. PCT/US03/21493	Applicant's or agent's file reference PCT MS0012Y	Date of informal communication (day/month/year) 10 August 2004 (10.08.2004)
Applicant MERCK & CO., INC		

<u>Communication</u> <input checked="" type="checkbox"/> by telephone <input type="checkbox"/> personal	<u>Participants</u> <input checked="" type="checkbox"/> Applicant: MERCK, & CO., INC <input checked="" type="checkbox"/> Agent: David Rubin <input checked="" type="checkbox"/> Examiner(s): Shaojia A. Jiang	<input checked="" type="checkbox"/> Identity checked <input type="checkbox"/> authorization checked <input type="checkbox"/> personally known
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Summary of communication:

Upon request by the examiner, applicant's representative David Rubin agreed to proceed to the 40th the International Preliminary Examination Report, directly in order to meet the administrative deadlines for the instant application and/or expedite the PCT process.

☐ An extension of time limit is granted (Form PCT/IPEA/427).

☒ A copy of this note is being sent to the applicant with Form PCT/IPEA/429.

PCT/IPEA/424.

Name and mailing address of the IPEA/US

Mail Stop PCT, Attn: IPEA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Form PCT/IPEA/428 (July 1992)

Authorized officer

Sreeni P. Manabhan
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